

Focus on Medical Management



Monitoring Compounds in Workers' Compensation



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I. Executive Summary



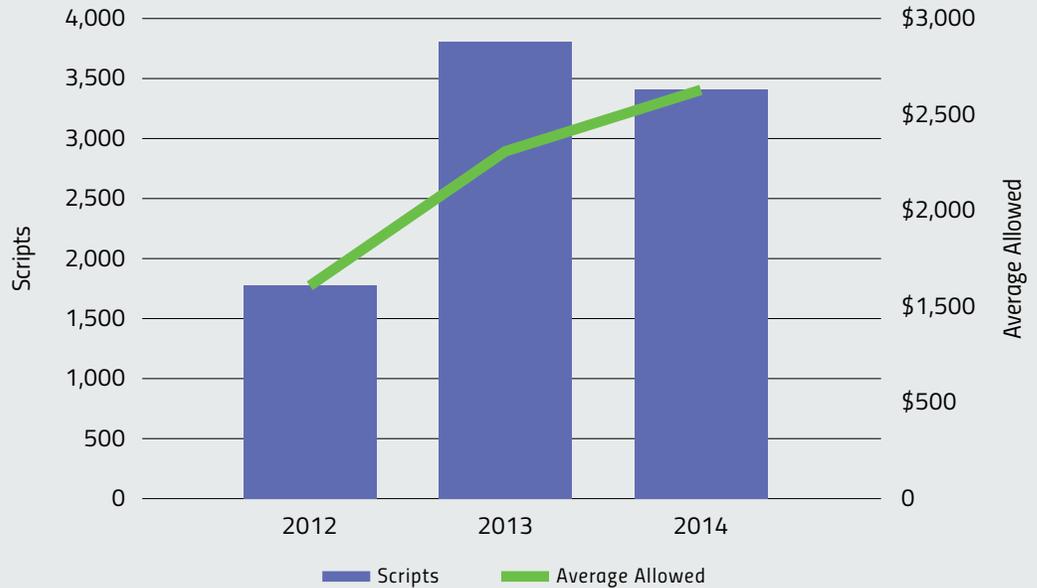
“As prescriptions for compounded drugs become more frequent, safety and necessity must be considered in order to effectively regulate their usage for workers’ compensation programs,” according to Rhonda Moran, Vice President, CorVel Corporation. Prospective management ensures all stakeholders are aware that a compound has been prescribed, and that proper documentation has been received indicating the compound is medically necessary considering patient safety, while also minding payors’ out-of-pocket costs. Remembering the end goal of providing safe, effective treatment to injured workers, compounds must be regulated out of interest of the patient and their employer.

II. Introduction

Three in four injured workers received opioids for pain relief in a study of 21 states conducted by the Workers’ Compensation Research Institute (WCRI). As the growing epidemic of opioid usage within workers’ compensation pain treatment continues to garner public attention – including the DEA’s recent reclassification of hydrocodone to a Schedule II drug – another pharmacy cost driver is also on the rise. Compounded medications, created as one-of-a-kind prescriptions, are becoming a sneaking suspicion within the healthcare management industry due to recent increases in usage and their corresponding high costs.

Compound Trends

In the U.S., while the number of compound scripts has declined slightly, the average allowed amount continues to increase each year.*



* Based on CorVel's book of business

Preliminary studies on the issue, including a study by the California Workers' Compensation Institute, support a growing trend among the specialty scripts, as compounded drugs in workers' compensation have increased by five times in the past five years. In fact, 2013 marked the first year that compounded medications were ranked among the top 10 drug classes. Consequently, rising concerns regarding patient safety and financial burdens on insurance payors are also becoming more apparent. While payors concentrate on pharmacy's latest buzz word "opioids," their attention may mistakenly overlook the parallel issue of compounds.

To combat this issue, employers must seek a partner that prospectively manages compounds to ensure the scripts that are being filled are medically necessary, safe for the individual and not just high-cost equivalents for what is already available in mass quantities in the marketplace.

III. The Dollar Sign Dilemma



Within the community of prescribing physicians, there are many physicians that have legitimate intentions when prescribing compounds to their patients after exhausting other treatment mediums. Industry experts have attributed increases in spending for compounds to trends of physicians trying to curb the industry's recent tendency to prescribe oral painkillers.

As such, some of these physicians work directly with the compounding pharmacists, while others have compounded medications readily available in their offices and are dispensing them to their patients. Additionally, many times these medications include several ingredients, resulting in a single prescription costing thousands of dollars.

Compounded medications are not regulated by the FDA because the medications are intended to be produced in a one-off fashion, in order to provide personalized treatments for specific patients. This means that the physicians – who may be dispensing – could either be mixing the prescriptions themselves, have staff mixing mass-produced prescriptions or are stocking mass-produced products, thus equating to industry concerns for product liability issues. First, the in-house compounded medications may not have adequate ingredients. And second, it cannot be assumed that the patient received the correct risk information, including warning labels and required paperwork. In addition, there is little evidence that compounds are more effective than commercially available drugs. As such, payors may be wary of pricey compounded prescriptions.

A Brief History

Compounded medications have been used for centuries, traced back to the days of the earliest apothecaries for the purpose of preparing personalized formulas from mixing medicines. In the United States, they reached their heyday in the early 1800s. With custom formulas ranging from flavored liquids to topical creams and sprays, compounds are intended to accommodate patients, specifically children and the elderly, who are unable to take prescribed medications in pill formats, as well as to help accommodate any allergies or sensitivities that a patient may have to various drugs or ingredients.

During the time that all drugs were compounded, the U.S. Food and Drug Administration (FDA) was created as a federal consumer protection agency in 1906 after the passage of the Pure Food and Drugs Act.

Around the 1950s, the advent of mass drug manufacturing caused compounding to decline rapidly. In time, the pharmacist role changed from a preparer to dispenser of medications.

Compounds in the News

A compound prescribed by an Orange County, California doctor led to the death of a five-month-old baby.

The baby's mother was prescribed a cream to treat her back pain resulting from a workers' compensation injury, which contained an antidepressant, pain reliever and cough suppressant. The compound cream was not properly labeled with her name, what the prescription was for or how to use it, according to the mother's attorney during the ongoing investigation. The patient applied the cream at home as instructed by her doctor and then tended to her baby, preparing his bottle, playing with him and letting him suck on her fingers.

The next morning the baby was unresponsive and had died due to multiple drug intoxication. The prescribing physician was indicted for involuntary manslaughter June 2014.

IV. Safety (and Necessity) First



"The safety and effectiveness of compounds are still uncertain due to the impracticality of validating 'one-off' medications when compared with a mass manufacturer," Moran said. Since compounds are not tested for safety or stability as indicated on the FDA's website, verifying safety and necessity is imperative before the prescription is filled.

The FDA does stipulate that a compounded product must be deemed necessary for a single identified patient under the Food and Drug Administration Modernization Act of 1997. Subsequently, it must not be a pre-existing, mass-produced drug, as in many instances a compound may have the same ingredients as a commercially available product. Necessity must be questioned by the payor. The burdens of safety and necessity may seem to fall into the hands of the employers; however, with proactive management and by seeking statements of medical necessity, the burden is then shifted to the prescriber to justify the compound.

Proactive solutions include implementing a trial of a compounded medication, as well as minimizing the number of ingredients within a compound. Using fewer ingredients allows the treating physician to better determine which active ingredients are impacting the patient's health.

Since compounded medications are not within the scope of the FDA's oversight, prescribers then must take responsibility and question compounds that are being increasingly marketed within the industry. The injured worker –

and his or her safety – comes first, and it is the responsibility of the prescriber to provide oversight where it is currently lacking in legislation.

Legislation Update

Some progress is being made. In November 2013, President Obama signed into law Title I of the Drug Quality and Security Act, of which sections 503 A and 503 B are related to the oversight of compounding drugs. Under these sections, the uncertainty regarding the validity of compounded medications was partially addressed. Specifically, under section 503 B, new legislation stated that a compounding pharmacy can register and pay a fee to be an outsourcing facility. Registered outsourcing facilities are listed online, where their compounding history is available publicly. As part of registration, a compounder must complete a comprehensive profile and participate in annual registration and audits every two years. Additionally, under the Drug Quality and Security Act, there are certain jurisdictions under which insurance carriers can deny drug payments to compounding pharmacies that are not registered as outsourcing facilities.

“With this legislation, the FDA has more oversight into compounding, which benefits both injured workers and payors,” Moran said. Coupled with these efforts, payors must continue to subscribe to the “safety first” philosophy and hold prescribers accountable.

V. Identification Issues



In the event that a compound has not been prospectively managed, they can be hidden within multiple lines of a bill and mistakenly paid. Many times a compound will show up as four or more lines on a bill – one for each ingredient. In certain instances, compounds may have a slight designation, such as “POW” to indicate powder or “TAB” to indicate tablet, but go unnoticed as the names of the ingredients that precede these indicators are similar to generic ingredients. This presents the identification issue.

Misidentified compounds can result in excessive, and sometimes extraneous, spend for payors despite specific fee schedules that may be in place. When a dispensing pharmacy processes a compound online within the payor’s Pharmacy Benefits Manager (PBM), the automated formulary can flag the compound to alert the bill review analyst. However, compounds that are processed and billed via paper bills do not have the system alert capability, making them susceptible to being dispensed and processed. To best prevent this issue, payors must consider a program that identifies compounds either electronically at the point of sale or retrospectively in order to then conduct utilization review.

Multiple ingredients, with seemingly common names are a constant for compound billing. Payors must have access to necessary resources to identify compounds, recognized visual coding practices and/or electronic means.

VI. Two Sides to Every Story

Despite concerns regarding the validity and safety of compounds, it cannot be denied that compounded medications can clinically benefit some patients. For patients with an allergy to inactive components within commercially available medications, compounds serve as an avenue for them to receive the treatment they need. That said, it is also important to note that the incidence of a true allergy to an inactive component of a marketed product is very low, according to the National Institute of Allergy and Infectious Disease.

As with many issues in the healthcare management industry, it is the quintessential paradigm of intended use versus abuse. Compounded medications are intended to give personalized care to a specific subset of patients. Prospective management is imperative when it comes to all compounds.

VII. Conclusion

In the heat of the issues surrounding pharmacy and opioids, compounds are emerging as yet another concern to industry payors. Whether compounded medications are being used according to their true purpose – to provide a one-of-a-kind medication for a patient with unique needs – or are instead used as a high-cost substitution for commercially available medications, payors must seek resources to help them manage the utilization of these prescriptions.

CorVel Corporation takes a prospective approach to management by requiring all compounds in their PBM to have prior authorization. By sending out communications, all stakeholders including the employer and the adjuster are aware of risks associated with compound utilization. Additionally, CorVel requires the prescriber to attain a Statement of Medical Necessity, in order to receive justification for the compound. Combined with attestations required from the pharmacy – on the part of the FDA – patient safety is at the forefront.

For compounds filled outside of the PBM, a series of bill review system alerts, requesting the same letters of medical necessity and attestation, helps cut excessive costs and reduce patient risk, as does CorVel's leverage within our network. Required justification for filling a compounded medication and proactive management are in the best interest of injured workers' health and payors' pharmacy spend.